

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION OF:)	
)	
NICOLAS PETER SHORTIS)	Electronically filed on
)	
U.S. SERIAL NO. 10/588,558)	June 24, 2009
)	
FILING DATE: August 4, 2006)	
)	
FOR: USE OF AMINOSALICYLATES IN)	
DIARRHOEA-PREDOMINENT)	
IRRITABLE BOWEL SYNDROME)	
)	
GROUP ART UNIT: 1614)	
)	
EXAMINER: Phyllis G. Spivack)	
)	
CUSTOMER NO. 23446)	
)	
CONFIRMATION NO. 8274)	

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

I, Thomas Julius Borody of Centre for Digestive Diseases Pty Limited, Department of Research & Innovation, Level 1, 229 Great North Road, Five Dock NSW 2046, Australia declare the following:

1. I am a Clinical Gastroenterologist and Medical Director of Centre for Digestive Diseases, a clinic set up for treating patients with various gastrointestinal disorders. I hold a Bachelor of Medical Science

(Honours) and Bachelor of Medicine both from University of New South Wales and hold a Doctorate in Medicine. I am also Adjunct Professor at the University of Technology Sydney and a Consulting Gastroenterologist at the Sydney Adventist Hospital and St. Vincent's Hospital in Sydney, Australia.

2. I have worked in diarrhoea predominant Irritable Bowel Syndrome condition therapy for the last 25 years.

3. I have used Balsalazide on numerous occasions to treat patients with diarrhoea predominant IBS.

4. I was the previous assignee of the invention of the present application from the inventor and have assigned the invention to Pharmatel (R&D) Pty Limited as trustee of the Pharmatel (R&D) Trust. I have read the above mentioned US patent application in detail.

5. In February 2004, the patent application would have enabled a person familiar with the technology involved in the patent application to administer the disclosed compounds (including Balsalazide) for the prophylaxis of non-inflammatory irritable bowel syndrome.

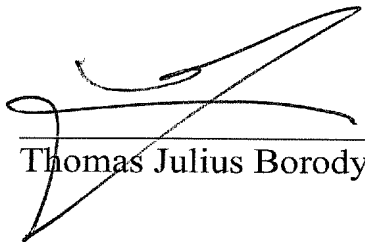
6. The person familiar with the technology involved in the application in early 2004 would understand that non-inflammatory irritable bowel syndrome is an episodic disorder that at times will "settle down" and at other times will "flare-up".

7. Reading the Examples in the patent application, the person familiar with the technology would have understood that the patients described there were treated for irritable bowel syndrome but that also the continued administration of the compound was having a **prophylactic effect** on the irritable bowel syndrome. In other words, once the ongoing "flare up" had settled down, the continued therapy

ended up being a prophylaxis preventing recurrence of the irritable bowel syndrome.

8. Hence, by simply reading the examples in the patent application, a person familiar with the technology would have understood how to, and would have been able to, achieve a prophylaxis of diarrhoea predominant irritable bowel syndrome.

9. I certify that all statements made herein of my own knowledge are true, and that all statements made herein on information and belief are believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.



Thomas Julius Borody

Date 22 May 2009